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EXAMINER
PORTER, RACHEL L

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/923,385	MICHELSON ET AL.	
	Examiner	Art Unit	
	Rachel L. Porter	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/14/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-15 and 129-151* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-15 and 129-151* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Notice to Applicant

1. Claims 2-15 and 129-151 are pending. This communication is in response to the Board decision mailed 1/31/06.

Response to BPAI Decision

2. In the decision by the Board of Patent Appeals and Interferences (BPAI) mailed 1/31/06, the rejections of claims 2-15 and 129-151 were reversed.

The basis for the reversal of claims, in substance, was that the Examiner should have granted the Applicant the benefit of the provisional priority date (Jan. 28, 2000 from application 60/178,634), for the feature of "automatically presenting a questionnaire associated with the given clinical study to the person or caregiver." In particular, the BPAI explained that the feature was enabled by Applicant's provisional application (60/178,634):

> It appears reasonable to us that the cited passage from page 9 of the provisional application does provide support, albeit not *verbatim* for "automatically presenting a questionnaire." The artisan would have understood from the system including software that supports "account sign-up, management, demographics capture, and personalization of target audiences;" from "behavioral data collection...and specified user views" that a user is indeed inputting information that is requested of him/her; i.e., there is some type of questionnaire presented to the user in order to acquire this information. Also, since there is a "comparison of the participant profile" (it appears that a participant profile would have been collected by responses to a questionnaire) "to the trials protocol criteria," it

is clear that questionnaire-entered data from a user is compared to clinical criteria.

As such, the Knight reference, (USPN 2002/0099570) was deemed invalid as prior art under 35 U.S.C. 102(e) for the instant application.

However, new grounds of rejection for the pending claims have been provided below.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8 and 137 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 currently recites that the notice is sent by "regular mail." It is unclear to the Examiner what the Applicant intends to claim or what the applicant deems to be "regular mail." For purposes of examination, the examiner will interpret any form of message delivery as paper mail and apply art accordingly.

Claim 137 recites that the questionnaire recites "wherein said questionnaire information regarding ***inclusion/exclusion*** criteria." Claim 137 is vague and indefinite because it is unclear whether the "/" is "and" or "or". For the purpose of applying art, the examiner will interpret the slash as an "or."

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2, 4,7,10-13 and 130-151 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, Gary, "System makes it easier to link patients to clinical trials"(hereinafter Baldwin" in view of information available at the website of CenterWatch (hereinafter CenterWatch) and Brown (USPN 6,196,970).

As per claim 2, Baldwin discloses a method for recruiting a person to participate as a subject in a clinical study (i.e. link patients to clinical trial)(title and abstract), comprising the steps of:

(a) presenting one or more web pages that allow the person or a caregiver associated with the person to register with a database by submitting registration information to the database (i.e. AOR Securenet is a secure extranet ... patient information is entered online...)(page 2), wherein the registration information includes at least one disease condition of interest to the person, contact information, and permission information indicating whether the person or caregiver wishes to receive notice of one or more clinical studies (i.e. ... if fuzzy match is made, an email alert with online link to trial information is sent to patient's physician ... open to select users. Clinicians, drug companies and administrators ...)(page 2-3);

(b) automatically registering the person or caregiver with the database upon receipt of the registration and permission information (see entire article);

(c) after step (b), automatically determining, in accordance with the permission information and the registration information, whether to provide the person or caregiver with notice of a given clinical study associated with a disease condition of interest to the person (i.e. ... if fuzzy match is made, an email alert with online link to trial information is sent to patient's physician ... open to select users. Clinicians, drug companies and administrators...)(pages 2-3);

(d) providing the person or caregiver notice of the given clinical study only if a determination is made in step (c) to provide such notice (i.e. ... if fuzzy match is made, an email alert with online link to trial information is sent to patient's physician... open to select users. Clinicians, drug companies and administrators ...)(pages 2-3);

Baldwin does not explicitly disclose

wherein the registration information includes at least a geographic location of the person.

However, CenterWatch discloses wherein the registration information includes at least a geographic location of the person (i.e. Patient Notification Service pages). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of Baldwin with the teaching of CenterWatch to include the collection of geographic location in the registration information of the person for the motivation of providing clinical trial matching information for patients and research

professionals interested in information on and/or participating in clinical trials (CenterWatch Home Page).

Baldwin and CenterWatch in combination do not explicitly disclose

(e) automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d); and

(f) storing answers submitted by the person or caregiver in the database .

However, Baldwin does disclose that after the patient has enrolled in a trial, the online system manages additional data collection and reporting. (Baldwin: par. 25) Brown discloses automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d) (i.e. trial specific questions)(col. 4, lines 3-15—the subject responds to the protocol associated with the clinical trial (i.e. research trial), which includes questions). Brown also discloses storing answers submitted by the person or caregiver in the database (col. 6, lines 19-27, lines 43-44—subject responses are sent back to the server and stored on the database). At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Baldwin and CenterWatch in combination to present questionnaires associated with the given clinical trial to the person/subject (or caregiver) and to store the responses submitted by the person/subject a database. As suggested by Brown, one would have been motivated to include these features to facilitate the aggregation and analysis of data from remote sites. (Brown: col. 3, lines 7-8)

As per claim 4, Baldwin and CenterWatch do not explicitly disclose the method of claim 2, wherein the questionnaire includes criteria specific to a clinical study for determining whether the person is an eligible subject for the given clinical study.

Brown discloses a method the questionnaire includes criteria specific to a clinical study for determining whether the person is an eligible subject for the given clinical study. (col. 4, lines 29-39;col. 6, lines 19-27, lines 43-44) Brown discloses a method wherein protocol feedback (i.e. including questionnaire responses) allow researchers to determine whether a subject or given population is responsive to the treatment in a study or if a new population should be targeted (i.e. new patients are eligible). At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art further modify the method of Baldwin and CenterWatch to include criteria within the questionnaire to determine whether the person is an eligible subject for the given clinical study. As suggested by Brown, one would have been motivated to include this feature to minimize fuzzy assessments made regarding a patients following a given a protocol, thereby imposing a more logical assessment upon subject assessment. (col. 4, lines 14-19)

As per claim 7, Baldwin discloses the method of claim 2, wherein the notice provided in step (d) is sent by electronic mail from a web site associated with the one or more web pages to an e-mail address of the person or caregiver (page 2).

As per claim 10, Baldwin does not explicitly disclose the method of claim 2, wherein a determination is made to provide the person or caregiver with the notice in step (c) in accordance with a geographic location of the given clinical study.

However, Baldwin does disclose wherein a determination is made to provide the person or caregiver with the notice in step (c) as discussed previously above. CenterWatch discloses providing notice of clinical studies in accordance with a geographic location of the given clinical study (CenterWatch Patient Notification service pages). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include notice of clinical studies in accordance with a geographic location of the given clinical study as disclosed by CenterWatch within Baldwin for the motivation of providing clinical trial matching information for patients and research professionals interested in information on and/or participating in clinical trials (CenterWatch Home Page).

As per claim 11, Baldwin discloses the method of claim 2, wherein in step (c) a determination is made not to provide the person or caregiver with notice of the given clinical study (i.e. fuzzy matches. The Examiner interprets this feature to read on clinical trials that the person or caregiver does not match)(page 2).

As per claim 12, Baldwin discloses the method of claim 2, wherein in step (a) the registration information includes whether the person is interested in clinical study

information, whether the person is interested in new medical therapies, or whether the person is interested in participating in clinical studies (page 2).

As per claim 13, Baldwin does not explicitly disclose the method of claim 2, wherein a determination is made to provide the person or caregiver with the notice in step (c) in accordance with a geographic location of an investigator associated with the study.

However, Baldwin discloses wherein a determination is made to provide the person or caregiver with the notice in step (c). CenterWatch discloses providing a list of clinical study(ies) in accordance with a geographic location of a clinical study as discussed previously above (the Examiner interprets the geographic determination limitation to include the geographic location of the clinical trial the investigator is associated with). It would have been obvious to one of ordinary skill at the time of Applicant's invention to include the geographic location matching of CenterWatch with the determination step of Baldwin for the motivation of providing clinical trial matching information for patients and research professionals interested in information on and/or participating in clinical trials (CenterWatch Home Page).

As to claims 130-136, Baldwin, CenterWatch, and Brown disclose the method of claim 2 as explained in the rejection of claim 2. Baldwin and CenterWatch do not explicitly disclose that questionnaire is a pre-examination questionnaire (e.g. screening questionnaire; pre-screening questionnaire) Brown discloses a method wherein

questionnaires are administered and data are collected at various points throughout research trial process (col. 4, lines 3-18; Figure 2b) Brown discloses that the research protocol maybe be modified, non-responders may be identified, and new subgroups within the subjects may be identified for alternate or different testing with different parameters (col. 4, lines 26-37) As such, the questionnaires provided to the patients may function as screening, pre-screening, and pre-examination questionnaires in identifying those who are not eligible (i.e. responding poorly to the protocol) or identifying those who will participate well or poorly in the trial (non-responsive or responsive to the questionnaires)

Brown further discloses a method the questionnaire wherein criteria specific to a clinical study for determining whether the person is an eligible subject for the given clinical study. (col. 4, lines 29-39;col. 6, lines 19-27, lines 43-44) Brown discloses a method wherein protocol feedback (i.e. including questionnaire responses) allow researchers to determine whether a subject or given population is responsive to the treatment in a study or if a new population should be targeted (i.e. new patients are eligible). At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art further modify the method of Baldwin and CenterWatch to include criteria within the questionnaire to determine whether the person is an eligible subject for the given clinical study. As suggested by Brown, one would have been motivated to include this feature to minimize fuzzy assessments made regarding a patients following a given a protocol, thereby imposing a more logical assessment upon subject assessment. (col. 4, lines 14-19)

As to claim 137, Baldwin, CenterWatch, and Brown disclose the method of claim 2 as explained in the rejection of claim 2. Baldwin does not expressly disclose that the questionnaire included inclusion or exclusion criteria. CenterWatch discloses a questionnaire that includes inclusion or exclusion criteria. (The Patient Notification pages ask the patients about their geographic location limits, whether they would like to know about drugs recently approved by the FDA; medical areas of interest—page 12 of website packet) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Baldwin with the teaching of CenterWatch to include exclusion or inclusion criteria on a questionnaire. One would have been motivated to include this feature to avoid wasting resources pursuing individuals who may no longer be interested in participating in a trial.

As to claims 138 and 150, the claims are substantially similar in scope to claim 131. As such, claims 138 and 150 are rejected for the reasons provided in the rejections of claims 2, 130, and 131, and incorporated herein.

As to claim 139 and 140, the limitations of the present claims are addressed by the rejection of claim 138.

As to claims 141-148, the claims are similar in scope to claims 130-137 and are rejected on the same basis.

As to claims 149 and 151, the limitations of the present claims are addressed by the rejection of claim 138.

7. Claims 3 and 129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, CenterWatch and Brown as applied to claim 2 above, and further in view of "TVisions wins Top Web Externet Award; Recognized for Creative, Life-Saving Site" (hereinafter TVisions).

As per claim 3, Baldwin, CenterWatch, and Brown do not explicitly disclose The method of claim 2, further comprising the step of:

(g) accessing the answers to the questionnaire along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f).

However, TVisions discloses accessing the answers to the questionnaire along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f) (i.e. additions and updates to the patient profile database and the clinical trial databases activates the SecureNet Trial Matching System ...)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include accessing the answers to the questionnaire along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f) as disclosed by TVisions within Baldwin, CenterWatch and Brown for the motivation of alerting physicians within seconds of possible matches of their patients with available or new clinical trials (page 2, second paragraph).

As per claim 129, the limitations of claim 129 are substantially similarly to claim 2 with the exception of "step e." Baldwin, CenterWatch and Brown disclose a method for recruiting a person to participate as a subject in a clinical study as explained in the rejection of claim 2 above.

Baldwin, CenterWatch, Brown do not explicitly disclose

(e) allowing the person or caregiver the opportunity to amend the registration information in the database during a subsequent visit to the web site.

However, TVisions allowing the person or caregiver the opportunity to amend the registration information in the database during a subsequent visit to the web site (i.e. additions and updates are to the patient profile database ...)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include storing answers submitted by the person or caregiver in the database as disclosed by TVisions for the motivation of alerting physicians within seconds of possible matches of their patients with available clinical trials and new clinical trials (page 2, second paragraph).

8. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, CenterWatch and Brown, as applied to claim 2, and in further view of Schmidt et al (USPN 6,839,687)

As per claim 5, Baldwin and CenterWatch a method for registering caregivers or individuals online and via the World Wide Web for clinical trials, as explained in the rejection of claim 2. Brown further discloses automatically generating questionnaires

and storing data for a person or caregiver on a database, as explained in the rejection claim 2.

However, Baldwin, Brown and CenterWatch do not explicitly disclose the method of claim 2, wherein steps (a) and (b) are performed during a registration visit by the person or caregiver to a web site associated with the one or more web pages, and step (g) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site (page 2).

Schmidt discloses a method wherein steps (a) and (b) are performed during a registration visit by the person or caregiver to a web site associated with the one or more web pages, (col. 2, lines 1-21, lines 27-34—information collection, eligibility determination and notification; col. 3, line 24-25—communication through Internet technology) and step (g) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site (col. 4, lines 54-67). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of Baldwin, Brown and CenterWatch in combination with the teaching of Schmidt to have steps (a) and (b) performed during a registration visit by the person or caregiver to a web site associated with the one or more web pages, and step (g) include notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site. As suggested by Schmidt, one would have been motivated to include these features to provide method and system for conducting medical studies which enables a simpler and more effective completion of the medical studies (col. 1, lines 65-67)

As per claim 6, Baldwin discloses the method of claim 5, wherein step (d) further includes providing a listing of information associated with the given clinical study in a personal library associated with the person or caregiver on the web site (Fig. 10 and Fig. 11).

9. Claims 8-9, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, CenterWatch, and Brown, as applied to claim 2, and in further view of Official Notice.

As to claims 8-9, Baldwin, CenterWatch, and Brown in combination do not explicitly disclose the method of claim 2, wherein the notice provided in step (d) is sent by "regular" mail or telephone to the person or caregiver. However, it is submitted that at time of the applicant's invention, the telephone and "paper mail" (i.e. snail mail) were old and well-known means of communicating requested information or notifications to individuals. At the time of the applicant's invention it would have been obvious to one of ordinary skill in the art to modify the method of Baldwin, CenterWatch, and Brown in combination to have the notice of step (d) sent by regular mail or telephone to the person or caregiver. As suggested by Brown, one would have been motivated to include these features to facilitate the aggregation and analysis of data from remote sites. (Brown: col. 3, lines 7-8)

As per claim 14. Baldwin, CenterWatch, and Brown teach the method of claim 2 as explained in the rejection of claim 2, but do not explicitly disclose the method of claim

2, wherein the answers submitted by the person or caregiver are provided by telephone, regular mail, facsimile, and other off-line sources. However, the Examiner takes official notice that at the time of the applicant's invention it was well known in the art to provide information by telephone, mail, fax, or other "offline sources" such as hand delivery. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention it would have been obvious to one of ordinary skill in the art modify the system of Baldwin, CenterWatch and Brown in combination to allow the person or caregivers to communicate answers by alternate means. One would have been motivated to include the alternatives to provide the customer with customer preferred delivery methods particularly with highly sensitive information.

10. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, CenterWatch and Brown as applied to claim 2 above, and further in view of Larkin, Marilynn, "Physicians accelerate onto the Internet" (hereinafter Larkin).

As per claim 15, Baldwin and CenterWatch do not explicitly disclose the method of claim 2, wherein the step of automatically determining further includes reference to genetic sequence information associated with a person registered in the database.

However, Larkin discloses clinical studies directed to particular genetic sequences and using online recruitment (page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the online patient recruitment of clinical studies for genetic studies within the Baldwin, CenterWatch and Brown in the method for the motivation of speeding up patient recruitment (i.e. within 6

months of the site's inauguration, 127 eligible woman ... By contrast, it took 4 years to recruit 395 volunteers with traditional methods ...)(see abstract and page 2)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel L. Porter whose telephone number is (571) 272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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